UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

)
IN RE: PHARMACEUTICAL INDUSTRY)
AVERAGE WHOLESALE PRICE LITIGATION)
)
THIS DOCUMENTS RELATES TO:)
) MDL No. 1456
County of Suffolk v. Abbott Laboratories, et al.) CIVIL ACTION NO. 01-12257-PBS
Civ. Action No. 1:03-cv-10643)
)

DEFENDANT ELI LILLY'S INDIVIDUAL RESPONSE TO SUFFOLK COUNTY'S SUPPLEMENTAL FILING IN RESPONSE TO THE COURT'S OCTOBER 26, 2004 ORDER

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On October 26, 2004 this Court directed Suffolk County to "disclose...all documents upon which it relied in calculating the spreads, and provide, in writing, a more definite statement of its method of calculation pursuant to Federal Rule of Civil Procedure 12(e)" before the Court would complete its ruling concerning the motions to dismiss filed by the "Suffolk 13" defendants, of which Eli Lilly and Company ("Lilly") is one. Lilly adopts and incorporates by reference the arguments set forth in the Response of the Suffolk 13 + 6, and provides the following additional information unique to Lilly's products.

I. Suffolk's Complaint and its November 16, 2004 Disclosure Rely on Irrelevant Data and Disingenuously Fail To Note Lilly's Publicly Published Wholesaler Pricing Data

The Lilly products mentioned in the Suffolk pleadings are the atypical antipsychotic Zyprexa® (olanzapine) and the antidepressant Prozac® (fluoxetine hydorchloride). Suffolk's allegations of fraud as to these products are based on an alleged "spread" between the Average Wholesale Price ("AWP") reported by Lilly in the RedBook, and an estimated wholesaler acquisition cost of Zyprexa and Prozac, a price term that Suffolk refers to as "true AWP." Suffolk's evidence of the wholesaler acquisition cost for Prozac® and Zyprexa® is nothing more than pure conjecture, and is limited to the application of the one-size-fits-all 1.27 "true AWP" estimate that is discussed at more length in the joint Response filed by the 13 + 6 defendants.

In relying solely upon the arbitrary 1.27 estimated multiplier, Suffolk fails to advise the Court that there is no need to estimate Lilly's wholesaler acquisition cost at all. Lilly regularly publishes wholesaler price lists that accurately report Lilly's prices to wholesalers for the two drugs at issue, and Suffolk does not allege (nor can it) that Lilly's published price lists are inaccurate. Lilly's wholesale price information has at all times been accessible to the County of Suffolk and the New York Medicaid program through widely available sources, including but not limited to the New York Medicaid program's pricing contractor, First Data Bank. The

published price lists definitively show that the 1.27 estimated multiplier used by Suffolk grossly overstates Lilly's actual wholesale price for these products.¹

II. Suffolk and the New York Medicaid Program did not overpay for Lilly's Products

Suffolk's contrived estimated pricing data are submitted in an effort to convince the Court that the County and the New York Medicaid program suffered losses because of Lilly's overcharging. The information collected by Suffolk in its marketplace study, however, in addition to suffering from the flaws noted in the joint pleading, also utterly fails to show that Medicaid paid more for Lilly's products than other retail customers.

In fact, Suffolk's data demonstrate the contrary. Even assuming that Lilly pays the minimum statutory rebate of 15.1% on these two drug products, Medicaid pays far less for these products than any of the surveyed retail customers.² In other words, even Suffolk's own self-styled research shows that the Medicaid program did not overpay for Lilly's products.

III. Suffolk's Assertion that Lilly is "Under Investigation" for its Pricing Practices is Grossly Misleading

Suffolk also alleges that Lilly is being "investigated" by the Senate Finance Committee³ and the Energy and Commerce Committee, an assertion that is both misleading and without context. The oversight powers granted to Congressional Committees that have spurred in-depth studies of the pharmaceutical industry are intended to assist the committees in studying industry practices for the purpose of legislating needed changes. The receipt of an inquiry from a

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The wholesaler acquisition cost for Prozac and Zyprexa is consistently 16 and 2/3% less than Lilly's reported AWP.

For example, the publicly available published data show that 10 mg Zyprexa was reimbursed at \$8.67 *before* a rebate of at least 15.1% (meaning a maximum net price of \$7.37), while Suffolk's 2003 market survey revealed consumer prices of \$8.90, \$8.37, and \$8.80.

The Senate Finance Committee itself does not refer to its communications with Lilly as an "investigation," but instead refers to the inquiry as a study of issues relating to Medicare and Medicaid coverage of prescription drug benefits.

Congressional Committee does <u>not</u> indicate that Congress has concluded that the recipient has committed fraud, as Congress' aim is to gain a broad industry perspective of pricing practices – including the good and the bad – in order to understand the effect of existing laws and to frame legislative changes.⁴

CONCLUSION

Suffolk's disclosure is wholly inadequate to demonstrate a credible basis for pursuing a fraud case against Eli Lilly and Company. Suffolk's allegations of fraud as to Lilly remain unsupported, vague, and ambiguous. Accordingly, Suffolk's claims against Lilly should be dismissed with prejudice.

Respectfully submitted,

Dated: November 30, 2004 /s/ Carolyn J. McElroy

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The Committees' investigative authority lies in Sections 1, 5, and 8 of Article I of the United States Constitution, which generally grant Congress "all legislative powers" and authorize Congress to "determine the rules of its proceedings[.] Pursuant to this grant of authority, the houses adopt resolutions setting forth the rules of substance and procedure that govern each session of Congress. Thus, for example, the Energy and Commerce Committee has been conducting its inquiry pursuant to House Rule X, which addresses "[g]eneral oversight responsibilities ... in order to assist the House in...its analysis, appraisal, evaluation of ... the application, administration, execution, and effectiveness of Federal laws...[and] conditions and circumstances that may indicate the necessity or desirability of enacting new or additional legislation."

CERTIFICATE OF SERVICE

I herby certify that on November 30, 2004 I caused a true and correct copy of Defendant Eli Lilly's Individual Response to Suffolk County's Supplemental Filing in Response to the Court's October 26, 2004 Order to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 by sending a copy to Verilaw for posting and notification.

/s/ Carolyn J. McElroy

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